K063676

X. 510(k) SUMMARY OF SAFTEY & EFFECTIVENESS

MAR 05 2007

PROPREIETARY NAME:	DBX® Demineralized Bone Matrix
COMMON NAME:	Bone Void Filler Containing Human Demineralized Bone Matrix (DBM)
PROPOSED REGULATORY CLASS:	Class II
CLASSIFICATION IDENTIFICATION:	21 C.F.R. §888.3045 Resorbable calcium salt bone void filler device
PRODUCT CODE:	MBP, MQV
PANEL CODE:	87—Orthopedic Devices
SPONSOR:	Musculoskeletal Transplant Foundation 125 May Street Edison, NJ 08837 732-661-0202 723-661-2189 fax

INDICATIONS FOR USE:

DBX® is intended for use as a Demineralized Bone Matrix for voids or gaps that are not intrinsic to the stability of the bony structure. It can be used in the:

Putty	**Mix**	**Paste**
Extremities	Extremities	Extremities
Pelvis	Pelvis	Pelvis
Posterolateral Spine	Spine	
Cranium		

DBX® is indicated for treatment of surgically created osseous defects or osseous defects created from traumatic injury. DBX® Putty can be used as an extender in the spine with autograft. DBX® Mix may be used as a bone void filler in the spine. DBX® can be used with bone marrow.

DBX® is for single patient use only.

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DEVICE DESCRIPTION:

DBX® is intended for single patient use only. DBX® Demineralized Bone Matrix is available in three forms: Paste, Putty and Mix. DBX® products are completely resorbable. DBX® Paste and Putty are composed of cadaveric cortical bone; the DBX® Mix is composed of cadaveric corticocancellous bone. The bone granules are mixed with sodium hyaluronate (NaHy) in varying combinations to form the DBX® Putty, Paste, and Mix. DBX® Putty is available in five sizes and DBX® Paste and Mix are available in four sizes.

SAFETY AND EFFECTIVENESS INFORMATION:

Biocompatibility of DBX® materials has been established through their long history of safe and effective clinical use, further supported by laboratory testing conducted per ISO 10993. DBX® is single-donor processed using aseptic techniques and is tested for sterility per current USP <71>.

OSTEOINDUCTIVITY POTENTIAL:

DBX® is osteoconductive, and has been shown to have osteoinductivity potential in an athymic mouse. Every lot of final product will be tested to ensure the osteoinductive potential of the final product. Osteoinduction assay results in the athymic mouse model should not be interpreted to predict clinical performance in human subjects.

VIRAL CLEARANCE AND INACTIVATION:

The method for processing the DBM contained in DBX® was evaluated for its viral inactivation potential. A panel of model potential human viruses representing various virus types, sizes, shapes and genomes were evaluated. The DBM processing methods were determined to provide significant viral inactivation potential for a wide range of potential viruses.

OSTEOINDUCTIVE POTENTIAL:

DBX® will be assayed *in vivo* for its osteoinductive potential. Standard testing performed in an athymic mouse must prove positive for lot release.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Musculoskeletal Transplant Foundation
% Ms. Nancy Bennewitz
Regulatory Affairs Submission Specialist
125 May Street
Edison, New Jersey 08837

MAR 0 5 2007

Re: K063676
Trade/Device Name: DBX® Demineralized Bone Matrix Mix
Regulation Number: 21 CFR 888.3045
Regulation Name: resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV, MBP
Dated: December 7, 2006
Received: December 11, 2006

Dear Ms. Bennewitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IV. INDICATIONS FOR USE

510(k) Number (if known): K063674

Device Name: DBX® Demineralized Bone Matrix

Indications for Use:

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Putty	Mix	Paste
Extremities	Extremities	Extremities
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DBX® is for single patient use only.

Prescription Use __X__ (Per 21 CFR 801 Subpart D) OR Over-The-Counter Use _____ (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063674